

REMARKS

Claims 19, 21, 22 and 24-41 were examined. In the instant Office Action, the Examiner has raised several issues, which are set forth by number in the order they are addressed herein:

- 1) Claims 19, 21, 22 and 24-41 stand rejected under 35 U.S.C. § 112 first paragraph, as allegedly lacking enablement;
- 2) Claims 19, 21, 22 and 24-41 stand rejected under 35 U.S.C. § 112 first paragraph, as allegedly lacking enablement;
- 3) Claims 19, 24-29 and 33-35 stand rejected under 35 U.S.C. § 112 first paragraph, as allegedly failing to meet the written description requirement;
- 4) Claims 26-28 and 33-35 stand rejected under 35 U.S.C. § 112 first paragraph, as allegedly failing to meet the written description requirement; and
- 5) Claims 19, 21, 22 and 24-41 stand rejected under 35 U.S.C. § 112 second paragraph, as allegedly indefinite.

Applicant hereby cancels Claims 19, 21, 22 and 24-41 and enters new Claims 42-51, in order to further the prosecution of the present application and Applicant's business interests, yet without acquiescing to the Examiner's arguments. Applicant reserves the right to prosecute the original, similar, or broader claims in one or more future application(s). Support for new Claims 42-51 directed to isolated peptides consisting of the amino acid sequence of SEQ ID NO:1 (p540), SEQ ID NO:2 (p865), SEQ ID NO:21 (p572, erroneously listed in the previous response as SEQ ID NO:16) or SEQ ID NO:22 (P572Y) can be found in the newly canceled claims and in the Specification (including but not limited to Tables 1, 2, 6 and 7). Further support can be found in, but is not limited to, the teaching in the Specification regarding the use of "synthetic peptides, synthetic peptides in immunological adjuvant, dendritic cells pulsed with synthetic peptides, naked DNA and RNA" (Specification, page 30, lines 4 and 5). Thus the amendments do not introduce new matter.

Applicant thanks the Examiner for the courteous second telephone Interview with their representative on March 1, 2007, and the helpful comments provided therein. Applicant's Interview Summary is attached to this paper (Tab A).

1 & 2) The Claims Are Enabled

The Examiner has rejected Claims 19, 21, 22 and 24-41 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. The Examiner states that the:

specification, while enabling for a composition for the in vitro induction of cytotoxic T lymphocytes that lyse cancer cells, in vitro, upon recognition of naturally processed human telomerase transcriptase peptides comprising at least one of a polypeptide consisting of nine amino acids wherein said peptides are SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:16, SEQ ID NO:22 does not reasonably provide enablement for a composition for induction of cytotoxic T lymphocytes that lyse [primary] cancer cells upon recognition of naturally processed human telomerase reverse transcription peptides comprising at least one HLA-A2.1 restricted TRT peptide nine amino acids in length of a human TRT protein consisting of a sequence set forth in SEQ ID NO:23 (Office Action, pages 2-15).

Applicant respectfully disagrees with certain characterizations of the art by the Examiner and respectfully disagrees that the claims lack enablement. The Specification and reports of record from Applicant's laboratory published in peer-reviewed journals, describe peptides consisting of amino acids SEQ ID NO:1 (p540), SEQ ID NO:2 (p865), SEQ ID NO:21 (p572, erroneously listed in the previous response as SEQ ID NO:16) or SEQ ID NO:22 (p572Y) as being suitable for induction of CTL that lyse human telomerase reverse transcriptase⁺ HLA-A2.1⁺ cancer cells. In particular, Table III discloses that CTL subjected to in vitro immunization with p540 (SEQ ID NO:1) and p865 (SEQ ID NO:2), lyse human, hTERT⁺, HLA-A2⁺ breast, colon, lung, melanoma and prostate cancer cells (Specification, page 24). Likewise, the Specification teaches that "CTL generated against p572 [SEQ ID NO:21] were able to lyse the hTERT⁺/HLA-A2⁺ melanoma cell line 624" (Specification, at page 27, lines 24-26) as illustrated in the dose-response curve of Figure 6. Lastly, the p572Y (SEQ ID NO:22) modified hTERT peptide of the instant application (Specification, tables on pages 27 and 28) was shown to be suitable for inducing CTL that lyse hTERT⁺/HLA-A2⁺ human myeloma U266 cells using the methods of the instant application as evidenced by Figures 4 and 5 of Hernandez (PNAS, 99:12275-12280, 2002 co-authored by Applicant).

Nonetheless as described above, Applicant has replaced the pending claims with a new claim set that does not recite a specific use for the recited peptides. In particular, Applicant has added new Claims 42-51 directed to isolated peptides consisting of the amino acid sequence of

SEQ ID NO:1 (p540), SEQ ID NO:2 (p865), SEQ ID NO:21 (p572, *erroneously listed in the previous response as SEQ ID NO:16*) or SEQ ID NO:22 (P572Y). These new claims do not recite an intended use, and indeed, are not limited to a particular intended use. As such, Applicant submits that the Examiner's rejection is moot and should be withdrawn.

3 & 4) The Claims Meet the Written Description Requirement

The Examiner has rejected Claims 19, 24-29 and 33-35 under 35 U.S.C. § 112 first paragraph, as allegedly failing to meet the written description requirement. The Examiner states:

the Specification does not describe the composition for induction of cytotoxic T lymphocytes that lyse cancer cells upon recognition of naturally-processed hTRT peptides wherein the composition comprises at least one HLA-A2.1-restricted hTRT peptide nine amino acid residues in length from SEQ ID NO:23, a modified peptide, in a manner that satisfies either the Lilly or Enzo standards (Office Action, pages 15-23).

Applicant respectfully disagrees that the pending claims fail to meet the written description requirement. Nonetheless as described above, Applicant has replaced the pending claims with a new claim set that does not recite this phrase. In particular, Applicant has added new Claims 42-51 directed to isolated peptides consisting of the amino acid sequence of SEQ ID NO:1 (p540), SEQ ID NO:2 (p865), SEQ ID NO:21 (p572, *erroneously listed in the previous response as SEQ ID NO:16*) or SEQ ID NO:22 (P572Y). Applicant believes that the new claim language obviates the written description rejections. Accordingly, Applicant respectfully requests that these rejections be withdrawn.

5) The Claims Are Definite

The Examiner as rejected Claims 19, 21, 22 and 24-41 under 35 U.S.C. § 112 second paragraph, as allegedly being indefinite. In particular, the Examiner has rejected the claims because of the phrase “naturally processed hTRT peptides” (Office Action, pages 23 and 24). Applicant respectfully disagrees that the claims are indefinite for inclusion of this phrase, suggested by the Examiner in a first telephone Interview conducted with Applicant's representative on April 20, 2006. Nonetheless as described above, Applicant has replaced the pending claims with a new claim set that does not recite this phrase. Applicant believes that the

new claim language obviates this rejection. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

CONCLUSION

Applicant believes the amendments and arguments set forth above traverse the Examiner's rejections and therefore request that these grounds for rejection be withdrawn. However, should the Examiner believe a telephone interview would aid in the prosecution of this application, the Applicant encourages the Examiner to call the undersigned collect.

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